

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

TRANSLATION
PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:		PCT WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)	
Date of mailing (day/month/year)		FOR FURTHER ACTION See paragraph 2 below	
Applicant's or agent's file reference P05-39			
International application No. PCT/JP2005/006138	International filing date (day/month/year) 30.03.2005	Priority date (day/month/year) 30.03.2004	
International Patent Classification (IPC) or both national classification and IPC			
Applicant SAKURA COLOR PRODUCTS CORPORATION			

1. This opinion contains indications relating to the following items:	
<input checked="" type="checkbox"/>	Box No. I Basis of the opinion
<input type="checkbox"/>	Box No. II Priority
<input type="checkbox"/>	Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/>	Box No. IV Lack of unity of invention
<input checked="" type="checkbox"/>	Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input type="checkbox"/>	Box No. VI Certain documents cited
<input type="checkbox"/>	Box No. VII Certain defects in the international application
<input checked="" type="checkbox"/>	Box No. VIII Certain observations on the international application
2. FURTHER ACTION If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220.	
3. For further details, see notes to Form PCT/ISA/220.	

Name and mailing address of the ISA/JP	Authorized officer
Facsimile No.	Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/006138

Box No. 1

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language
_____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2005/006138

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	2, 3, 8, 11, 14, 18-20, 24-32	YES
	Claims	1, 4-7, 9, 10, 12, 13, 15-17, 21-23	NO
Inventive step (IS)	Claims		YES
	Claims	1-32	NO
Industrial applicability (IA)	Claims	1-32	YES
	Claims		NO
2. Citations and explanations:			
<p>Document 1: JP 2002-303618 A (Fujimori Kogyo Co., Ltd.), 18 October 2002</p> <p>Document 2: JP 2001-174449 A (Sakura Color Products Corp.), 29 June 2001 & US 2001/054374 A1</p> <p>Document 1 (paragraphs 0009-0020, 0022, 0025, 0033-0035) describes an indicator that spreads on a surface of nonwoven fabric an indicator that contains a binder and a compound that changes hue through reaction with hydrogen peroxide. Sulfophthalene compounds and alizarine compounds are listed as compounds with this hue change. It also says it is possible to combine and use two or more compounds. It also says a dye or cosmetic that does not lose color or change color due to sterilization treatment and that does not damage the hue of the main pigment component may be added.</p> <p>Document 2 (claim 1 to claim 7, paragraphs 0019-0034) describes a plasma sterilization detection ink composition consisting of an anthraquinone dye, amide resin, alkyltrimethyl ammonium salt (a cationic surfactant), and a pigment component that does not change color in a plasma sterilization treatment atmosphere. Also described are using a cellulose resin as a resin binder, adding silica gel as an extending agent, and the desirability of making the resin binder 5 to 35 weight% of the ink composition. Also, it describes a plasma sterilization indicator formed with a color change layer consisting of the ink composition and a non-color-change layer that does not change color in a plasma sterilization treatment atmosphere. It says that this indicator has excellent stability and does not return to the original color after a color change, and it can reliably detect a plasma sterilization treatment, and that it is possible to freely control the detection sensitivity and color change speed, and that it is possible to perform quantitative measurement.</p>			

WRITTEN OPINION OF THE
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International application No.

PCT/JP2005/006138

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 30 and 32 refer to "the enclosing body described in claim 21" but the term "enclosing body" does not appear in claim 21. Therefore its said mention in claims 30 and 32 is in appropriate.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

The inventions of claims 1 and 4-7 do not possess novelty on account of document 1.

The sulfophthalene compounds and alizarine sodium sulphonate in the invention described in document 1 are respectively equivalent to the triarylmethane dyes and anthraquinone dyes of this application. It also says it is possible to combine and use two or more compounds, and appears to disclose combining and using sulfophthalene compounds (triarylmethane dyes) and alizarine sodium sulphonate (anthraquinone dyes).

The inventions of claims 2, 3, and 8 do not involve an inventive step on account of document 1.

Claims 2 and 3 adjust the composition by adding a cationic surfactant to an indicator that contains an anthraquinone pigment (see JP 2001-174449 A, claim 2, and JP 2003-325649 A, paragraph 0037). Therefore adding a cationic surfactant to the composition described in document 1 could be appropriately performed by a person skilled in the art, and using a alkyltrimethyl ammonium salt, isoquinolinium salt, imidazolinium salt, or pyridinium salt as the surfactant used when doing so could be appropriately selected by a person skilled in the art.

Regarding claim 8, providing a non-color-change layer that does not change color due to hydrogen peroxide in the indicator described in document 1 would easily be carried out by a person skilled in the art.

The inventions of claims 9, 10, 12, 13, 15-17, and 21-23 do not possess novelty on account of document 2.

Regarding claim 10, the amide resin in the invention described in document 2 is equivalent to the polyamide in the invention described in claim 10 of this application.

Regarding claim 22, it appears that cracks occur in the surface of the color change layer when forming the color change layer on the base material in the ink composition described in document 2.

The inventions of claims 11, 14, 18-20, and 24-32 do not involve an inventive step on account of document 2.

Regarding claim 11, selecting a reaction product of a dimer of linoleic acid and a di or polyamine as the amide resin described in document 2 would easily be carried out by a person skilled in the art.

Regarding claim 14, a combination of a plurality of resins is used as the binder in the ink composition. Document 2 says it is possible to use a cellulose resin as a binder. Therefore, using both an amide resin and a cellulose resin would easily be carried out by a person skilled in the art.

Regarding claims 18 and 19, document says that in addition to an anthraquinone dye, other dyes or cosmetics may coexist in the composition. Also, a pigment that reacts to hydrogen peroxide is used in a plasma sterilization detection ink composition. Therefore adding a component that changes color due to reaction with hydrogen peroxide to the ink composition described in document 2 would easily be carried out by a person skilled in the art. Selecting an alkyltrimethyl ammonium salt (see JP 2001-13129 A, paragraphs 0009, 0018) as the pigment used in an indicator of the hydrogen peroxide plasma sterilization type would easily be carried out by a person skilled in the art.

Supplemental Box

V

Regarding claim 20, adding an organic amine compound to an indicator composition for plasma sterilization is well-known (see JP 2002-303618 A, paragraph 0023). Therefore adding an organic amine compound to the indicator composition described in document 2 would easily be carried out by a person skilled in the art.

Regarding claims 24-26, providing a layer that changes color by reacting with hydrogen peroxide as an indicator for detecting plasma sterilization is well-known. Therefore providing a colored layer that changes color due to hydrogen peroxide in the indicator described in document 2 would easily be carried out by a person skilled in the art. Also, when doing so, forming the colored layer and the color change layer so that they overlap, or forming the colored layer and the color change layer so that they do not overlap each other in a striped or dotted pattern would easily be carried out by a person skilled in the art.

Regarding claims 27-29, providing an indicator for plasma sterilization inside a polyethylene enclosing bag is commonly practiced (see WO 98/46279 A, page 7 line 17 to page 8 line 16). Providing the indicator described in document 2 inside a polyethylene enclosing bag would easily be carried out by a person skilled in the art.

Regarding claim 31, the indicator described in document 2 can freely control detection sensitivity and color change speed, and can perform quantitative measurement. Therefore making adjustments so that the relevant indicator's color change indicates the end of plasma sterilization would easily be carried out by a person skilled in the art.

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Applicant

SAKURA COLOR PRODUCTS CORPORATION

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Inventive step (IS)	Claims		YES
	Claims	1-32	NO
Industrial applicability (IA)	Claims	1-32	YES
	Claims		NO

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Document 2 (claim 1 to claim 7, paragraphs 0019-0034) describes a plasma sterilization detection ink composition consisting of an anthraquinone dye, amide resin, alkyltrimethyl ammonium salt (a cationic surfactant), and a pigment component that does not change color in a plasma sterilization treatment atmosphere. Also described are using a cellulose resin as a resin binder, adding silica gel as an extending agent, and the desirability of making the resin binder 5 to 35 weight% of the ink composition. Also, it describes a plasma sterilization indicator formed with a color change layer consisting of the ink composition and a non-color-change layer that does not change color in a plasma sterilization treatment atmosphere. It says that this indicator has excellent stability and does not return to the original color after a color change, and it can reliably detect a plasma sterilization treatment, and that it is possible to freely control the detection sensitivity and color change speed, and that it is possible to perform quantitative measurement.

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